B. 510(k) SUMMARY (as required by 21 CFR 807.92)

MAY 1 3 2014

Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesive with Applicator Tip
February 10, 2014

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

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TRADE NAME: Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives

COMMON NAME: Topical Skin Adhesive

REGULATION NUMBER: 878.4010 – Tissue adhesive

PRODUCT CODE: MPN

REVIEW PANEL: General & Plastic Surgery

SUBSTANTIAL EQUIVALENCE

Aesculap, Inc. believes that the Aesculap Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives with Applicator Tip are substantially equivalent to Aesculap's current Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives (K111959 and K121976).

DEVICE DESCRIPTION

Histoacryl and Histoacryl Blue are sterile liquid topical skin adhesives composed of n-butyl-2-cyanoacrylate monomer. The two products are different in only one respect: Histoacryl is provided as a colorless liquid, and Histoacryl Blue is colored with the dye D&C Violet #2 with intent to ease visualization of the device during application.

Histoacryl Flexible Topical Skin Adhesive is a sterile liquid topical skin adhesive composed of n-butyl-2-cyanoacrylate monomer, softener, stabilizer, and colorant (D&C Violet #2).

The Histoacryl, Histoacryl Blue and Histoacryl Flexible are provided in 0.5 ml single patient use plastic ampoules. Each ampoule is sealed within a foil pouch so the exterior of the ampoule can remain sterile. The applicator tip is packaged in a sterile blister pack. The plastic ampoules and applicator tips will be packaged together in a box. The tissue adhesives remain liquid until exposed to water or water-containing substances including tissue, after which it cures (polymerizes) and forms a film that bonds to the underlying surface.

In vitro studies have shown that Histoacryl acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties and a correlation between microbial barrier properties and a reduction in infection have not been established.

INDICATIONS FOR USE

Histoacryl, Histoacryl Blue and Histoacryl Flexible topical skin adhesives are intended for topical application to hold closed easily approximated skin edges of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations. Histoacryl, Histoacryl Blue and Histoacryl Flexible may be used in conjunction with, but not in place of, deep dermal sutures.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The technological characteristics of the Aesculap Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives with Applicator Tip are equivalent in performance to the predicate devices Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives (K111959 and K121976). The subject device is shown to be substantially equivalent and has the same performance characteristic to the predicate devices through comparison in technology, Indication For Use, mechanism of action, intended application and performance. Both Histoacryl and Histoacryl Blue Topical Skin Adhesive and Histoacryl Flexible Topical Skin Adhesive devices use n-butyl-2-cyanoacrylate to facilitate wound closure. Histoacryl Flexible is designed to bond to the skin to provide flexible wound closure maintaining wound approximation.

In vitro studies have shown that Histoacryl acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties and a correlation between microbial barrier properties and a reduction in infection have not been established.

The differences between the proposed devices Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives with Applicator Tip and Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives are:

- The Histoacryl family will be packaged with a separate sterile blistered applicator tip. The applicator tip is an elastic elastomer which can be placed on the tip of the ampoule. The proposed devices will be packaged as a pack. Equal number of ampoules and applicator tips will be packaged together.

BIOCOMPATIBILITY:

The biocompatibility testing of the adhesive that was previously conducted for the currently marketed devices, Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives (K111959 and K121976) per ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" is deemed supportive of the proposed devices, Aesculap Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives with Applicator Tip. There were no changes to the formulation of the adhesive; therefore, no additional biocompatibility testing of the adhesive was conducted.

Testing was conducted in accordance to USP 31, <661> Containers, Plastics and <88> Biological Reactivity Tests, *In Vivo*. Biocompatibility testing within this submission was performed on the raw material from which the applicator tip is manufactured which includes the following: MEM Elution cytotoxicity (ISO 10993-5), intracutaneous irritation (ISO 10993-10), systemic toxicity (ISO 10993-11) and maximization sensitization (ISO 10993-10). In addition cytotoxicity testing was performed on the finished applicator tip. Based on the results from these studies, the proposed device is considered to be non-cytotoxic and non-irritants

PERFORMANCE TESTING

Testing was performed in accordance to FDA's Class II Special control Guidance Document for Tissue Adhesive for the Topical Approximation of Skin to demonstrate that the Aesculap Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives with Applicator Tip is substantially equivalent to other predicate devices. The following comparative testing demonstrated substantially equivalent performance to Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives.

- Wound closure strength (ASTM F2458-05)
- Peel adhesion strength (ASTM F2256-05)
- Lap-shear strength (ASTM F2255-05)
- Flexibility
- Heat of polymerization
- Ease of Expression
- Occlusion test
- Adhesive delivered per area
- Film thickness
- Set-time

Microbial barrier testing was conducted using Histoacryl and Histoacryl Flexible applied with the applicator tip. The method was a strike through test that was conducted with common organisms known to cause infections and represent gram positive, gram negative, motile and non-motile as well as fungi. The challenge was at a minimum concentration of 1×10^6 cfu.

STERILIZATION AND SHELF-LIFE:

Sterilization of Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives remains the same as the predicates (K111959 and K121976). The sterilization process consists of 1) ETO sterilization of the ampoule, 2) gamma radiation sterilization of the aluminum pouch: both are sterilized before 3) the sterility of the liquid topical skin adhesive which is guaranteed by membrane filtration and aseptic filling.

The applicator tip is blister packed and sterilized by ethylene oxide. Accelerated aging data for the applicator tip has been generated to support this submission.

CONCLUSION:

Based on the nonclinical testing Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives with Applicator Tip have been demonstrated to be substantially equivalent to Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 13, 2014

Aesulap® Incorporated
Ms. Kathy A. Racosky
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K140343
Trade/Device Name: Histoacryl, Histoacryl Blue and Histoacryl
Flexible Topical Skin Adhesives with Applicator Tip
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: February 12, 2014
Received: February 14, 2014

Dear Ms. Racosky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140343

Device Name

Histoacryl, Histoacryl Blue and Histoacryl Flexible Topical Skin Adhesives with Applicator Tip

Indications for Use *(Describe)*

Histoacryl, Histoacryl Blue and Histoacryl Flexible topical skin adhesives are intended for topical application to hold closed easily approximated skin edges of minimum-tension wounds from clean surgical incisions and simple, thoroughly cleansed, trauma-induced lacerations. Histoacryl, Histoacryl Blue and Histoacryl Flexible may be used in conjunction with, but not in place of, deep dermal sutures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joseph Nielsen -S
2014.05.13 07:16:03 -04'00'

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